



DEPARTMENT OF HEALTH & HUMAN SERVICES

RB 5/17/99 mason

Certified/Return Receipt Requested

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

May 13, 1999

WARNING LETTER

Steven J. Knoll, President
Knoll Patient Supply, Inc.
1112 SW 6th Avenue
Topeka, KS 66606-1456

KAN #99-020

Dear Mr. Knoll:

Recently an inspection was made of your liquid medical oxygen transfilling operation located at the above address. This inspection was conducted on April 6 and 9, 1999, by a Food and Drug Administration Investigator from this office who documented deviations from the Current Good Manufacturing Practice (CGMP) Regulations (Title 21, Code of Federal Regulations, Part 211). These deviations cause the liquid medical oxygen transfilled at this location to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act).

Significant deviations include, but are not limited to the following:

- failure to routinely assay incoming liquid oxygen for identity prior to filling cryogenic home units, and failure to document the witnessing of liquid oxygen testing when picked up at your distributor [21 CFR 211.165(a)];
- failure to perform and document required prefill operations on each cryogenic home vessel; failure to establish the reliability of the supplier's certificate of analysis through appropriate validation of the supplier's test results, by conducting an audit of the supplier at least annually [21 CFR 211.84(d)(3)];
- failure to establish written procedures designed to assure that the liquid oxygen has the identity and strength it purports or is represented to possess [21 CFR 211.100(a)];
- failure to have a documented procedure describing the responsibilities of the quality control unit [21 CFR 211.22(a)].


This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court injunction against further marketing of your liquid medical oxygen. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,



W. Michael Rogers
District Director
Kansas City District

(for)

CRP:tlw